

## **Memorandum of Meeting**

**Date:** November 24, 2003  
**Place:** Parklawn, Rockville, MD, Room 6-05  
**Subject:** Health Claim Petition- Glucosamine/Chondroitin Sulphate and Osteoarthritis

### **Participants:**

#### **Food and Drug Administration**

Center for Food Safety and Applied Nutrition

Office of Nutritional Products, Labeling and Dietary Supplements

Christine Taylor, Ph.D., Director (HFS-800)

Kathleen Ellwood, Ph.D., Director, Nutrition Labeling and Programs Staff (HFS-830)

Paula Trumbo, Ph.D., Team Leader, Nutrition Labeling and Programs Staff (HFS-830)

Craig Rowlands, Ph.D., Regulatory Review Scientist, Nutrition Labeling and Programs Staff (HFS-830)

#### Office of Director

Alan Rulis, Ph.D., Senior Advisor for Applied Nutrition

#### Center for Drug Evaluation and Research

Jim Witter, M.D.

#### Office of the Commissioner

Lester Crawford, D.V.M., Ph.D., Deputy Commissioner

Scott Gottlieb, M.D.,

#### Office of Chief Council

Dan Troy, Esq.

Mike Landa, Esq.

Louisa Nickerson, Esq.

#### **Emord and Associates P.C.**

Jonathon Emord, Esq.

Claudia Lewis-Eng

Andrea Ferreuz

Michael Glade, Ph.D.

Charles Simone, M.D.

#### **Weider Nutrition**

Dan Thomson

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Todd Crowley

**Michigan State University**

Michael Orth

This meeting was held at the request of Jonathon Emord on behalf of his client Weider Nutrition. The purpose of the meeting was to discuss the October 3, 2003 letter in which the Agency denied their petition because the claims were drug claims rather than health claims. This meeting provided an opportunity for the petitioner to state their reasons for why they believe the claims to be disease risk reduction claims and not drug/treatment claims. This petition requested that FDA authorize health claims for glucosamine and chondroitin sulfate, and (1) Osteoarthritis; (2) Osteoarthritis-related joint pain, tenderness, and swelling; (3) Joint degeneration; and (4) cartilage deterioration.

Mr. Emord discussed first amendment issues in the wording of the claim. Mr. Emord's scientific consultants discussed the scientific basis for how glucosamine and chondroitin sulfate affect the signs and symptoms of osteoarthritis.

FDA representatives discussed the elements of what is necessary for a health claim and how these differ from a drug/treatment type of claim. They discussed data that would be necessary for a health claim.

An FDA representative asked Mr. Emord to submit their position in writing so that the Agency may give further consideration, which he agreed to do.

Kathleen C. Ellwood, Ph.D.

cc: FDA meeting participants